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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,790	04/21/2004	Igor Dimitriesich Polyakov	3/400-5-C5	5045

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EXAMINER	
MINNIFIELD, NITA M	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,790	POLYAKOV ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 16, 2005 has been entered.

2. Claims 7-18 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment to the claims and/or comments, with the exception of those discussed below.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 7-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a dermatomycosis vaccine comprising inactivated dermatophytes, wherein the inactivated dermatophytes consists of the 8 dermatophytes defined in claim 7, or various combinations (4 to 7 dermatophytes) of these 8 dermatophytes as set forth in claims 8-17.

The specification does not set forth enablement of a vaccine comprising 4 or more inactivated dermatophyte strains. Examples 1-3 and Tables 9-10 have been reviewed. It is not clear what Applicants used in the vaccine composition. Example 1, page 18 indicates that "[A]fter 2 days, 125 ml of each culture in suspension is taken and mixed in a single container. The vaccine may be prepared by mixing together various combinations of the given strain." Exactly what was the composition of the vaccine administered that gave the results found in Tables 9 and 10? It is not clear if all 8 dermatophytes were used or some combination of 3, 4, 6 or 7 dermatophytes. It is not clear that the specific combination of 3 dermatophytes as set forth in claim 2 were used. It is not clear what dermatophytes in the vaccine gave rise to the vaccine protection that is shown in Table 10. Does Applicant intend for "immunogenic response" to mean that vaccine protection has been established, see page 11, or "establishing immunity" to mean vaccine protection has been established, see Tables 1-7?

The specification has not taught how to use the claimed vaccine. Mixing each culture in a single container or mixing together various combinations of the given cultures is set forth. However, it is not clear which composition (all 8 cultures in one container or various combinations of less than 8 cultures and if less than 8 cultures specifically which ones) was used to generate the data found on tables 9 and 10 of the specification. Which cultures provide protection against ringworm infection in an animal? Does the vaccine comprising a combination of cultures protect in the same manner as the individual cultures; is there a synergistic affect with regard to protection against ringworm infection?

There does not appear to be support or enablement for a vaccine consisting of just one antigen from one dermatophyte or a vaccine consisting of just one

dermatophyte, *T. verrucosum*. The art teaches the use of multiple dermatophytes in a vaccine composition, not a single dermatophyte, or single antigen from a single dermatophyte (Pier et al, 1995, 5284652; Sarkisov et al 4368191).

Gudding et al (Can. Vet. J., 1995) teaches that in animals vaccinated with inactivated vaccines, some protection is observed after challenge. However, the protective immunity is inadequate in most cases (abstract; p. 303, column 2). Further, the inactivated vaccine against ringworm must be capable of eliciting both humoral and cellular immune responses, of which the cellular response is crucial for protection and adjuvants are important in stimulating the cellular branch of the immune system (pp. 303-304). In view of the state of the art it is not clear if protection has been established against ringworm infection when Applicants state (see tables 1-7) "establishes immunity". It is not clear what type of immunity has been established. Applicants' vaccine composition does not recite a carrier or adjuvant, however Gudding indicates that the adjuvants are important in stimulating the cellular branch of the immune system and that the cellular branch is crucial for protection.

In view of the above discussion, there would be undue experimentation necessary for a person of skill in the art to practice the claimed invention.

The rejection is maintained for the reasons of record. Applicant's arguments filed April 5, 2005 have been fully considered but they are not persuasive. The Polyakov Declaration under 37 CFR 1.132 filed April 5, 2005 is insufficient to overcome the rejection of claims 7-18 based upon 112, first paragraph lack of enablement as set forth in the last Office action.

Applicants have asserted that they have provided sufficient guidance in the specification which, when combined with the routine methods commonly known in the art, render routine the preparation and use of the claimed vaccines. Applicants have directed the Examiner to various sections of the specification that indicate how to make and use the claimed invention. In particular, Applicants point to page 18 that states, "the vaccine may be prepared by mixing together various combinations of the given strains". However, this passage doe not indicate which combinations of the many possible would yield a vaccine to protect a subject against dermatomycosis as claimed.

Applicants have asserted that the immunogenic response produced by immunization of an animal with a vaccine comprising a single inactivated strain, as described in Tables 1-7 establishes (results in) immunity to that strain. The Examiner agrees that administration of a single inactivated strain establishes immunity, however an immune response does not establish vaccine protection against dermatomycosis as presently claimed by Applicants.

With regard to the Polyakov Declaration under 37 CFR 1.132, paragraph 5 states that the "vaccine of the present invention were prepared essentially according to the method disclosed in the above identified application." Paragraph 6 of the declaration states, "There are minor, insubstantial differences between the method for preparing the vaccines disclosed in the above identified application and the methods described herein. Such minor differences include: cultivating temperature (varied between 25°C and 28°C), time of cultivation (varied between 25 and 28 days), and the composition of the aqueous solution containing fermented hydrolyzed muscle protein (varied between 0.3 to 1%), glucose (varied between 5 to 10%) and yeast extract (varied between 0.1 to 1%). It is in the knowledge and

reflects the practice of a person skilled in the art that these parameters are alterable within the small ranges mentioned above, without resulting in significant change to the properties of the vaccines."

However, this is not sufficient to overcome the 112, first paragraph rejection. The experiment parameters (i.e. cultivating temperature, time of cultivation, composition of aqueous solution) are not the same as those set forth in the pending specification. The cultivating temperature in the specification (see Example 1, page 18) is 26°C, not a range of 25°C and 28°C. The time of cultivation stated in the specification is 15 days, not a range of 25 and 28 days. The declaration strains were cultivated a minimum of 10 days longer than those strains in the specification. The composition of the aqueous solution is not the same. The specification used 1% fermented hydrolyzed muscle protein, not a range of 0.3 to 1%. The glucose concentration in the specification is 10%, not the range of between 5 to 10%. The specification uses 1% yeast extract, not the varied between 0.1 to 1% as stated in the declaration. The strains were not prepared *essentially* according to the method disclosed in the pending application. The method used in the declaration is not commensurate in scope with the method set forth in the pending specification. The specification does not set forth any ranges of experimental parameters with regard to culturing the various strains; the specification sets forth an exact set of parameters for culturing the strains. The procedures described in the declaration the same as those described in the specification. In order for a declaration to provide support for enablement of the claimed invention the results/data shown in the declaration have to have been performed by the exact same (i.e. identical) procedure as described in the filed specification.

The rejection is maintained for the reasons of record. Applicant's arguments filed December 16, 2005 have been fully considered but they are not persuasive.

Applicants have asserted that "U.S. Patent 6,872,399 (the '399 patent), which issued on the parent application to the subject application, claims a vaccine composition comprising three (3) specific dermatophyte strains (claim 1) and a vaccine composition comprising eight (8) specific dermatophyte strains. The subject application provides support for vaccine compositions having more than three dermatophyte strains (see specification at page 17, lines 4-9, pat. page. 16, lines 10-25, at page 3, lines 11-13 and at page 18, lines 24-25), including a vaccine composition having eight dermatophyte strains. The issuance of the '399 fully supports such position. The Examiner's arguments over failure to comply with Section 112 are not understood in view of the issuance of the '399 patent. The subject application has claims directed to a vaccine composition comprising four (4) specific dermatophyte strains and a vaccine composition comprising seven (7) specific dermatophyte strains. Such combinations are fully supported by the specification.

However, as previously stated, it is the Examiner's position that the specification does not set forth enablement of a vaccine comprising 4 or more inactivated dermatophyte strains. Examples 1-3 and Tables 9-10 have been reviewed. It is not clear what Applicants used in the vaccine composition. Example 1, page 18 indicates that "[A]fter 2 days, 125 ml of each culture in suspension is taken and mixed in a single container. The vaccine may be prepared by mixing together various combinations of the given strain." Exactly what was the composition of the vaccine administered that gave the results found in Tables 9

and 10? It is not clear if all 8 dermatophytes were used or some combination of 3, 4, 6 or 7 dermatophytes. It is not clear that the specific combination of 3 dermatophytes as set forth in claim 2 were used. It is not clear what dermatophytes in the vaccine gave rise to the vaccine protection that is shown in Table 10. Further, the specification has not taught how to use the claimed vaccine. Mixing each culture in a single container or mixing together various combinations of the given cultures is set forth. However, it is not clear which composition (all 8 cultures in one container or various combinations of less than 8 cultures and if less than 8 cultures specifically which ones) was used to generate the data found on tables 9 and 10 of the specification. Which cultures provide protection against ringworm infection in an animal? Does the vaccine comprising a combination of cultures protect in the same manner as the individual cultures; is there a synergistic affect with regard to protection against ringworm infection?

5. Claims 7-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of US Patent 6872399. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a dermatomycosis vaccine comprising inactivated dermatophyte strains.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

This rejection is maintained for the reasons of record. It is noted that copending application 10/085703 is now US Patent 6872399. Applicants

respectfully request that this rejection be addressed when the claims are found to be allowable the subject matter of the claims may be amended during prosecution.

This rejection is maintained for the reasons of record. Applicant's arguments filed December 16, 2005 have been fully considered but they are not persuasive.

With regard to the obvious-type double-patenting rejection, Applicants have stated that a terminal disclaimed will be submitted to ensure that any patent issuing on the subject application will have the same term as the '399 patent.

This rejection will be maintained until a properly filed terminal disclaimer has been accepted.

6. No claims are allowed.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
January 20, 2006